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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,120	12/30/2003	Richard Boyd	NOR-015CP2 and 286336.154	3284

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EXAMINER	
SAUNDERS, DAVID A	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
07/16/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/749,120	BOYD ET AL.	
	Examiner	Art Unit	
	David A. Saunders	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-57,61-64,66-84,89,90,92 and 94-100* is/are pending in the application.

4a) Of the above claim(s) *43,61-64,66-84,90,92 and 94-98* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-42,44-57,89,99 and 100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

AMENDMENT ENTRY

Amendment of 4/10/07 has been entered. Claims 38-57, 61-64, 66-84, 89-90, 92, 94-100 are pending. Claims 38-42, 44-57, 89 and 99-100 are under examination. The amendment of 4/10/07 has entered no new matter.

ELECTION OF GROUP

Applicant's election with traverse of Group I (claims 38-57, 89 and 99-100) in the reply filed on 4/10/07 is acknowledged. The traversal is on the ground(s) that the searches for Groups I-III and VI "overlap" in their classes and subclasses. This is not found persuasive because even though there is some degree of overlap in their classes and subclasses, there would still be a requirement to use different search terms, in conjunction with in the classes and subclasses, for searching the different inventions. Also, there would be a requirement to use different search terms in searching the non-patent literature. As previously noted, in the restriction of 10/6/06, a search of the non-patent literature would be unlikely to any one reference showing or suggesting all of the recited methods of monitoring in the different Groups.

Additionally, even if it could be argued that the claims of all of Groups I-III and VI could be readily searched together, there would be an undue burden to examine all of the inventions in one application, because any one reference that might be found may not be equally applicable to the claims of all of the Groups, or to all of the dependent claims within one group. This is because applicant has filed an extensive number of related applications at different dates and, thus, the claims of all of the different Groups, or all of the dependent claims within one Group, need not have the benefit of the same effective filing date. Applicant has thus created a tremendous search burden for any one of the inventions, by virtue of the fact that he has filed a large number of his own applications which require searching for descriptive support of the invention now claimed. Applicant is, therefore, required to have only one invention searched in one application.

The requirement is still deemed proper and is therefore made FINAL.

ELECTION OF SPECIES

1) Applicant's election with traverse of "chemical castration", as the species of the method of disrupting sex-steroid mediated signaling, in the reply filed on 4/10/07 is acknowledged. The Office concurs that claims 38-42, 44-57, 89 and 99-100 of Group I read upon this election of species. The Office considers that "chemical castration" (in claim 44) and "administration of a pharmaceutical" (in claims 45-49) would have common embodiments; thus claims 45-49 will be examined with claim 44.

2) Applicant's election with traverse of leuprolide, as a species of pharmaceutical, in the reply filed on 4/10/07 is acknowledged.

3) Applicant's election with traverse of Factor Thymique Serique (FTS), as a species of the blood/serum marker, in the reply filed on 4/10/07 is acknowledged. The Office will consider "thymulin" as also elected, since "thymulin" is the active form of FTS, obtained when Mg++ becomes complexed with FTS (see Goya et al ref attached to response of 4/10/07

The traversal with respect to the election of species, in the first case, among methods of disrupting the sex steroid mediated signaling pathway is that there would be no undue burden to search all of the methods. This is not found persuasive because the different methods of disrupting the sex steroid mediated signaling pathway would not be findable with the use of any common search terms, whether one is searching the patent or the non-patent literature.

The traversal with respect to the election of species requirement, in last two cases, is on the ground(s) that the number of species in each case is only a "few". This is not found persuasive because irrespective of the fact that "few" is a relative term, the different recited species of pharmaceuticals and the different recited species of blood/serum markers are not structurally related. For example, the various pharmaceuticals recited in claim 46 have different recognized functions and different recognized structures (e.g. the LFRH antagonists and LFRH agonists have different recognized functions, and the different LFRH agonists recited in claim 47 would have different structures, such that different subclasses would need to be searched in classes 424 or 514). Even if there were to be common or overlapping subclass searches for the different recited pharmaceuticals or markers, there would still be a requirement to use different search terms, in conjunction with in the classes and subclasses, for searching the different species. Also, there would be a requirement to use different search terms in searching the non-patent literature. As previously noted, in the restriction of 10/6/06, a search of the non-patent literature would be unlikely to any one reference showing or suggesting all of the recited pharmaceuticals or markers for monitoring. The Office will consider other species of pharmaceuticals or markers, to the extent that these may be found in references submitted in an IDS or in an Office search.

OBJECTION(S) TO CLAIMS

Applicant is advised that should claim 45 be found allowable, claim 44 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing

one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The Office considers that "administration of a pharmaceutical" (in claim 45) and "chemical castration" (in claim 44) would certainly have common embodiments. It is not possible to determine from the disclosure whether one of these methods would have any embodiments which would not be encompassed by the other. In the event that applicant considers that one of these methods would have embodiments which would not be encompassed by the other, such embodiments must be specifically pointed out, and the corresponding sections of the disclosure must be specifically pointed out by page and line numbers.

Claims 46-48 and 100 are objected to because of the following informalities: these claims appear to recite numerous pharmaceuticals which are trademarked names. If so, each of these should be recited with all capital letters and be followed by the trademark symbol. Appropriate correction is required.

REJECTION(S) UNDER 35 USC 112, SECOND PARAGRAPH

Claims 38-49, 56-57, 89 and 99-100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "early" in claims 38 and 89 is a relative term which renders the claims indefinite. The term "early" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 89 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 89, "increase in the level of the marker" is indefinite because one does not know what serves as a baseline level, so that one would know that there has been any "increase in the level" above such a baseline.

REJECTION(S) UNDER 35 USC 112, FIRST PARAGRAPH

Claim 57 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment of 8/13/04 has entered new matter in claim 57.

Specifically, no "member of the keratinocyte growth factor family" was originally disclosed except for KGF per se. See para. [0237] of applicant's disclosure, as printed in US 2005/0042679 (cited on PTO-892).

REJECTION(S) UNDER 35 USC 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 38-39, 42, 44-46, 48, 50-57, 89 and 99 are rejected under 35 USC 103(a) as being unpatentable over Coy et al (5,073,624 cited in IDS of 8/11/04) in view of both

of Fabris (ref A55 cited in IDS of 8/11/05) and Mocchegiani et al (ref A150 in IDS of 8/11/04).

Coy et al show teach administration of an LH-RH antagonist to rejuvenate the thymus of patient with AIDS (e.g. col.2, lines 53-59; col. 5, lines 42-52). Fabris et al teach that FTS/thymulin can be detected in the blood stream and that this thymic factor "strictly reflects the functional activity of the thymus" (pg 533, col. 1, 2nd para.). Similarly, Fabris et al teach that, when regrowth/rejuvenation of the thymus was obtained by hormonal manipulation, thymus regrowth was "always associated with recovery of active thymulin plasma level" (pg 538, col. 1, 1st full para.).

Thus Fabris et al clearly suggest the use of FTS/thymulin as a blood marker of functional activity of the thymus. Since it is conventional for one to monitor the effects of any administered pharmaceutical, it would have been obvious to have used FTS/ thymulin as a blood marker of functional activity of a thymus that one is seeking to rejuvenate by administration of an LH-RH antagonist, such as that of Coy et al.

Mocchegiani et al teach that Growth hormone (GH, which is not a pharmaceutical agent capable of "disrupting the sex-steroid-mediated signaling to the thymus") may be administered to GH deficient humans (e.g. children deficient in GH) and that activity of the thymus can be monitored by determining blood plasma levels of thymulin. They show that thymulin levels rise within a 2 day observation period (legend to Fig. 2), which is clearly an "early increase". Mocchegiani et al thus buttress the obviousness rejection by teaching that it was known how to assay for blood plasma levels of thymulin and by

teaching the claimed feature that that thymulin levels rise within a time period, which is an "early increase".

All aspects of claims 38 and 44-46 and 89 are thus shown by the combination of references.

Regarding claim 39, AIDS is a disease consistent with the claim limitations.

Regarding claim 42, AIDS is a disease mostly found in post pubertal patients (except for cases such as in infants born to mothers with AIDS).

Regarding claim 48, since Coy et al show teach administration of an LH-RH antagonist to rejuvenate the thymus, it would have been obvious to use any known, commercially available LH-RH antagonist to rejuvenate the thymus.

Regarding claim(s) 50-55, as far as the examiner can determine from the poorly reproduced copy of ref A150, the rise in FTS/thymulin level is initiated "within about 24 hours".

Regarding claim(s) 56-57, FTS/thymulin is a "thymopoietic hormone"; see Moochegiani et al at page 248, col. 1.

Regarding claim 99, the recited mechanism would be an indirect effect of an LH-RH antagonist.

CONTACTS

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, whose telephone number is 571-

272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 7/9/07 DAS

David A Saunders

DAVID A. SAUNDERS
PRIMARY EXAMINER